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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411, 412, 419, 488, 489, and 495

[CMS-1785-CN2 and CMS-1788-CN2]

RINs 0938-AV08 and 0938-AV17

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership; and Medicare Disproportionate Share Hospital (DSH) Payments: Counting Certain Days Associated with Section 1115 Demonstrations in the Medicaid Fraction; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule; correction.

SUMMARY: This document corrects technical errors in the final rule that appeared in the August 28, 2023 **Federal Register** titled "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership; and Medicare Disproportionate Share Hospital (DSH) Payments: Counting Certain Days Associated with Section 1115 Demonstrations in the Medicaid Fraction" (referred to hereafter as the "FY 2024 IPPS/LTCH PPS final rule").

DATES: *Effective date*: This correcting document is effective November 9, 2023.

Applicability date: This correcting document is applicable for discharges beginning October 1, 2023.

FOR FURTHER INFORMATION CONTACT: Mady Hue, (410) 786–4510, and Andrea Hazeley, (410) 786–3543, MS–DRG Classifications.

SUPPLEMENTARY INFORMATION:

I. Background

This correcting document identifies and corrects errors in FR Doc. 2023-16252 of August 28, 2023 (88 FR 58640). The corrections in this correcting document are applicable to discharges occurring on or after October 1, 2023, as if they had been included in the document that appeared in the August 28, 2023 **Federal Register**.

II. Summary of Errors

On pages 58734 and 58735, we are correcting the omission of a comment and response with respect to the request for MS-DRG reassignment of cases reporting spinal fusion procedures utilizing an aprevo™ customized interbody fusion device.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rulemaking in the **Federal Register** before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Social Security Act (the Act) requires the Secretary to provide for notice of the proposed rulemaking in the **Federal Register** and provide a period of not less than 60 days for public comment. In addition, section 553(d) of the APA, and section 1871(e)(1)(B)(i) of the Act mandate a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the notice and comment and delay in effective date APA requirements; in cases in which these exceptions apply, sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act provide exceptions from the notice and 60-day comment period and delay in effective date requirements

of the Act as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process are impracticable, unnecessary, or contrary to the public interest. In addition, both section 553(d)(3) of the APA and section 1871(e)(1)(B)(ii) of the Act allow the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest and an agency includes a statement of support.

We believe that this final rule correction does not constitute a rule that would be subject to the notice and comment or delayed effective date requirements. This document corrects technical errors in the preamble of the FY 2024 IPPS/LTCH PPS final rule, but does not make substantive changes to the policies or payment methodologies that were adopted in the final rule. As a result, this final rule correction is intended to ensure that the information in the FY 2024 IPPS/LTCH PPS final rule accurately reflects the policies adopted in that document.

In addition, even if this were a rule to which the notice and comment procedures and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the final rule or delaying the effective date would be contrary to the public interest because it is in the public's interest for providers to receive information regarding the relevant Medicare payment policy in as timely a manner as possible, and to ensure that the FY 2024 IPPS/LTCH PPS final rule accurately reflects our policies. Furthermore, such procedures would be unnecessary, as we are not altering our payment methodologies or policies, but rather, we are simply implementing correctly the methodologies and policies that we previously proposed, requested comment on, and subsequently finalized. This final rule correction is intended solely to ensure that the FY 2024 IPPS/LTCH PPS final rule accurately reflects these payment methodologies and policies. Therefore, we believe we have good cause to waive the notice and comment and effective date requirements. Moreover, even if these corrections were considered to be retroactive rulemaking, they would be authorized under section

1871(e)(1)(A)(ii) of the Act, which permits the Secretary to issue a rule for the Medicare program with retroactive effect if the failure to do so would be contrary to the public interest. As we have explained previously, we believe it would be contrary to the public interest not to implement the corrections in this final rule correction for discharges occurring on or after October 1, 2023, because it is in the public's interest for providers to receive information regarding the relevant Medicare payment policy in as timely a manner as possible, and to ensure that the FY 2024 IPPS/LTCH PPS final rule accurately reflects our policies.

IV. Correction of Errors

In FR Doc. 2023-16252, appearing on page 58640 in the *Federal Register* of Monday, August 28, 2023, the following corrections are made:

1. On page 58734, third column, after the fourth full paragraph, the language is corrected by adding the following:

"Another commenter (the manufacturer of the aprevo™ customized interbody spinal fusion devices) reiterated its request to reassign cases reporting the performance of a spinal fusion procedure utilizing an aprevo™ customized interbody spinal fusion device from the lower severity (without CC/MCC) MS-DRGs to the higher severity (with MCC) MS-DRGs. According to the commenter, CMS's analysis as discussed in the proposed rule confirmed that cases reporting the use of aprevo™ contained average costs that exceeded the average costs of every spinal fusion MS-DRG.

The commenter expressed strong disagreement with CMS' characterization of the reliability of the Medicare claims data and stated that it can verify the utilization of the aprevo™ technology with absolute certainty at both the provider and patient level, which the commenter referred to as legitimate claims data. Moreover, the commenter stated that it is their access to precise procedure data for the aprevo™ spinal fusion device that enabled the commenter to notify CMS of discrepancies identified by the manufacturer with the Medicare claims data. Specifically, the commenter stated that it has continued to collect claims data from its customers

and that there is now data on 77 claims based on legitimate customer utilization of the aprevo™ device. The commenter stated that approximately half of these 77 claims are documented in CMS's Standard Analytical File (SAF) FY 2022 Q1-Q4 report, and half of the 77 claims are customer claims which were provided directly by hospitals to the commenter, representing procedures occurring in Q1 FY 2023 and not yet reflected in CMS's Limited Data Set (LDS) files. The commenter provided the following table.

DRG	Case #	LOS	STANDARDIZED Implantable Device Charge**$	STANDARDIZED Total Charge $	aprevo Case 0278 Charges % Increase Over Cases in Same MS-DRG	aprevo Case 0278 Charges $ Increase Over Cases in Same MS-DRG
MS-DRG 453 all cases	3,900	9	$124,141	$333,609		
MS-DRG 453 legitimate cases using aprevo custom-made interbody device		9	**$229,691**	**$506,670**	**85%**	**$105,550**
MS-DRG 454 all cases	19,830	4	$101,607	$227,461		
MS-DRG 454 legitimate cases using aprevo custom-made interbody device		6	**$243,041**	**$448,126**	**139%**	**$141,434**
MS-DRG 455 all cases	17,490	3	$77,389	$171,430		
MS-DRG 455 legitimate cases using aprevo custom-made interbody device		3	**$158,688**	**$314,285**	**105%**	**$81,299**
MS-DRG 456 all cases	1,300	13	$98,952	$317,228		
MS-DRG 456 legitimate cases using aprevo custom-made interbody device			no data	no data		
MS-DRG 457 all cases	3,060	6	$94,230	$229,958		
MS-DRG 457 legitimate cases using aprevo custom-made interbody device		3	**$301,681**	**$470,774**	**220%**	**$207,451**
MS-DRG 458 all cases	810	3	$77,290	$171,541		
MS-DRG 458 legitimate cases using aprevo custom-made interbody device		2	**$99,327**	**$185,619**	**29%**	**$22,037**
MS-DRG 459 all cases	3,200	10	$63,211	$232,841		
MS-DRG 459 legitimate cases using aprevo custom-made interbody device		6	**$377,687**	**$740,473**	**497%**	**$314,476**
MS-DRG 460 all cases	31,120	3	$51,914	$137,734		
MS-DRG 460 legitimate cases using aprevo custom-made interbody device		3	**$169,818**	**$302,750**	**227%**	**$117,904**
TOTAL CASES USING APREVO CUSTOM-MADE INTERBODY DEVICE					**% Increase Over MS-DRG 453 Implant Charges ($124,141)**	**$ Increase Over MS-DRG 453 Implant Charges ($124,141)**
Aprevo SAF FY22 Q1-Q4	36	5.83	$242,308	$457,465	95%	$118,167
Aprevo Carlsmed Data FY23	41	4.49	$198,433	$374,242	60%	$74,292
All Aprevo Cases	**77**	**5.12**	**$218,946**	**$413,151**	**76%**	**$94,805**

Notes:

**** Based on revenue center 278 "Other Implants".** https://resdac.org/cms-data/variables/revenue-center-code-ffs

The commenter provided findings from its own analysis of claims in CMS's SAF data and stated an analysis of the customer claims in CMS's SAF data that were verified by the commenter demonstrated a significant increase in charges for revenue center 0278 (Implantable Devices) over the average implantable device charges for the highest CC level MS-DRG (MS-DRG 454). The commenter stated that this implantable device charge data proved beyond doubt that the increased total charges of legitimate customer claims in CMS's own data is attributable to the higher cost of the aprevo™ custom-made anatomically designed devices.

The commenter also stated that CMS has a long-standing policy of using external data to inform MS-DRG reclassification as a way of addressing concerns about the timeliness of data from the MedPAR file. According to the commenter, CMS accepts the submission of external data that is intended to demonstrate that inpatient stays involving a new technology are costlier on average than the other inpatient stays in the same MS-DRG.

With respect to the revised code proposal, the commenter stated that while it agreed that the revised procedure code descriptions will improve the reporting of procedures that utilize the aprevo™ spinal fusion device by eliminating a misinterpretation of the current description that it stated has caused illegitimate uses of the codes, it continues to have concerns as it relates to the requested MS-DRG assignment and rate-setting for cases reporting use of the aprevo™ spinal fusion device for FY 2024. The commenter stated that Medicare claims data reflecting improved coding as it relates to aprevo™ utilization will not be available when the FY 2025 rulemaking process is underway. The commenter stated that if CMS chooses to wait another year to act it will compromise beneficiary access to an important technology that provides significant health benefits.

Additionally, the commenter stated that while the new technology add-on payment for the transforaminal interbody fusion (TLIF) indication will continue for FY 2024, the new technology add-on payment for the anterior lumbar interbody fusion (ALIF) and lateral lumbar

interbody fusion (LLIF) procedures, which represent 70 percent of aprevo™ utilization, expires on September 30, 2023. According to the commenter, if CMS does not assign all procedures reporting the use of an aprevo™ spinal fusion device to MS-DRGs 453 and 456 for FY 2024, it will risk beneficiary access to this important technology."

2. On page 58735, top half of the page, third column, after the first partial paragraph, and before the first full paragraph, the language is corrected by adding the following paragraphs:

"As discussed in the FY 2024 IPPS/LTCH PPS proposed rule and prior rulemaking, we generally utilize MedPAR data when considering changes to the MS-DRG classifications, which includes an analysis of the volume of cases, the average length of stay, and average costs, with consideration of other factors. For the FY 2024 IPPS/LTCH PPS proposed rule, our initial analysis of potential changes to the MS-DRG classifications was based on ICD-10 claims data from the September 2022 update of the FY 2022 MedPAR file, with certain additional analysis based on ICD-10 claims data from the December 2022 update of the FY 2022 MedPAR file.

In the July 30, 1999 IPPS final rule (64 FR 41499 through 41500), we stated that in order for us to consider using non-MedPAR data, the non-MedPAR data must be independently validated, meaning when an entity submits non-MedPAR data, we must be able to independently review the medical records and verify that a particular procedure was performed for each of the cases that purportedly involved the procedure. In this particular circumstance, where external data for cases reporting the use of an aprevo™ spinal fusion device was provided, CMS did not have access to the medical records to conduct an independent review; therefore, we were not able to validate or confirm the non-MedPAR data submitted by the commenter for consideration in this final rule. However, our work in this area is ongoing, and we will continue to examine the data and consider these issues as we develop potential future rulemaking proposals."

Elizabeth J. Gramling,

Executive Secretary,

Department of Health and Human Services.

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